

DOCKET NO.: TJU-2858



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Scott A. Waldman

Confirmation No.: Not Yet Assigned

Application No.: 10/621,684

Group Art Unit: Not Yet Assigned

Filing Date: July 17, 2003

Examiner: Not Yet Assigned

For: ST RECEPTOR BINDING COMPOUNDS AND METHODS OF USING THE SAME

DATE OF DEPOSIT: Aug. 18, 2003

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

TYPED NAME: Elizabeth A. McLoud

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).



In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:
- ☐ Certification in Accordance with § 1.97(e) is attached; or
- ☐ The fee of **\$180.00** as set forth in § 1.17(p) is attached.
- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:
- ☐ Certification in Accordance with § 1.97(e) is attached;
- or
- ☐ The fee of **\$180.00** as set forth in § 1.17(p) is attached.
- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **\$180.00** as set forth in § 1.17(p).
- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith

## EXCEPT THAT:

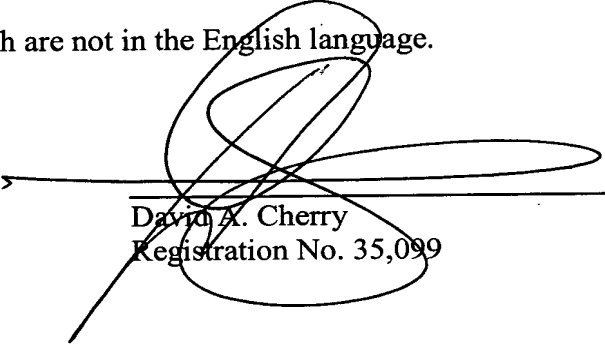
- ☒ In view of the voluminous nature of reference 4, and the likelihood that this reference is available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☒ Copies of references **1-55 and 91** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **08/141,892**, filed **October 26, 1993** now **U.S. Patent No. 5,518,888**; copies of references **56-59 and 92-97** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **08/305,056**, filed **September 13, 1994** now **U.S. Patent No. 5,601,990**; copies of references **60-84, 90, 98-110 and 133** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **08/468,449**, filed **June 6, 1995**; copies of references **85-89** listed on the attached Form PTO-1449 were previously cited by

or submitted to the Patent and Trademark Office in prior Application No. 08/467,920, filed June 6, 1995 now U.S. Patent No. 5,962,220; copies of references 111-132 listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. 08/583,447, filed January 5, 1996.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ There are no listed references which are not in the English language.

Date: 8/18/03

  
David A. Cherry  
Registration No. 35,099

WOODCOCK WASHBURN LLP  
One Liberty Place - 46th Floor  
Philadelphia, PA 19103  
Telephone: (215) 568-3100  
Facsimile: (215) 568-3439



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	Docket No. TJU-2858	Application No. 10/621,684
	Applicant Scott A. Waldman	
	Filing Date July 17, 2003	Group Not Yet Assigned
	Confirmation No. Not Yet Assigned	

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	<b>1</b>	Almenoff et al., "Ligand-based Histochemical Localization and Capture of Cells Expressing Heat-Stable Enterotoxin Receptors", <i>Mol. Microb.</i> , <b>1993</b> , 8, 865-873
	<b>2</b>	Bjorn et al., "Antibody-Pseudomonas Exotoxin A Conjugates Cytotoxic to Human Breast Cancer Cells In Vitro", <i>Cancer Research</i> , <b>1986</b> , 46, 3262-3267
	<b>3</b>	Bjorn et al., "Evaluation of Monoclonal Antibodies for the Development of Breast Cancer Immunotoxins", <i>Cancer Research</i> , <b>1985</b> , 45, 1214-1221
	<b>4</b>	Bodansky et al., "Peptide Synthesis", John Wiley and Sons, 2d Ed., (1976)
	<b>5</b>	Burgess et al., "Biological Evaluation of a Methanol-Soluble, Heat-Stable <i>Escherichia coli</i> Enterotoxin in Infant Mice, Pigs, Rabbits and Calves", <i>Infect. Immun.</i> , <b>1978</b> , 21, 526-531
	<b>6</b>	Cawley et al., "Epidermal Growth Factor-Toxin A Chain Conjugates: EGF-Ricin A is a Potent Toxin While EGF-Diphtheria Fragment A is Nontoxic", <i>Cell</i> , <b>1980</b> , 22, 563-570
	<b>9</b>	Chan et al., "Amino Acid Sequence of Heat-stable Enterotoxin Produced by <i>Escherichia coli</i> Pathogenic for Man", <i>J. Biol. Chem.</i> , <b>1981</b> , 256, 7744-7746
	<b>10</b>	Chung et al., "Enzymatically Active Peptide from the Adenosine Dithosphate-Ribosylating Toxin of <i>Pseudomonas aeruginosa</i> ", <b>1977</b> , 16, 832-841

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
-----------------	------------------------

\* A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous and easily obtainable by the Examiner.



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. TJU-2858	Application No. 10/621,684
		Applicant Scott A. Waldman	
		Filing Date July 17, 2003	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	11	Cohen, M. et al., "Receptors for <i>Escherichia coli</i> Heat Stable Enterotoxin in Human Intestine and in a Human Intestinal Cell Line (Caco-2)", <i>J. Cell. Physiol.</i> , <b>1993</b> , 156, 138-144	
	12	Corstens, F. et al. "Chemotactic peptides: New Locomotion for Imaging of Infection?", <i>J. Nucl. Med.</i> , <b>1991</b> , 32(3), 491-494	
	13	Cumber et al., "Preparation of Antibody-Toxin Conjugates", <i>Meth. Enzymol.</i> , <b>1985</b> , 112, 207-225	
	14	Currie et al., "Guanylin: An endogenous Activator of Intestinal Guanylate Cyclase", <i>Proc. Natl. Acad. Sci. USA</i> , <b>1992</b> , 89, 947-951	
	15	de Sauvage, F. et al., "Primary Structure and Functional Expression of the Human Receptor for <i>Escherichia coli</i> Heat-stable Enterotoxin", <i>J. Biol. Chem.</i> , <b>1991</b> , 266, 17912-17918	
	16	Dreyfus et al., "Chemical Properties of Heat-Stable Enterotoxins Produced by Interotoxigenic <i>Escherichia coli</i> of Different Host Origins", <i>Infect. Immun.</i> , <b>1983</b> , 42, 539-548	
	17	Drewett, J. et al., "The Family of Guanylyl Cyclase Receptors and Their Ligands", <i>Endocrine Reviews</i> , <b>1994</b> , 15(2), 135-162	
	18	Eckelman et al., "Comparison of <sup>99m</sup> Tc and <sup>111</sup> In Labeling of Conjugated Antibodies", <i>Nucl. Med. Biol.</i> , <b>1986</b> , 13, 335-343	
	19	Evans et al., "Difference in the Response of Rabbit Small Intestine to Heat-Labile and Heat-Stable Enterotoxins of <i>Escherichia coli</i> ", <i>Infect. Immun.</i> , <b>1973</b> , 7, 873-880	
	20	Fischman, Alan J. et al., "A Ticket to Ride: Peptide Radiopharmaceuticals", <i>J. Nucl. Med.</i> , <b>1993</b> , 34(12), 2253-2263	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

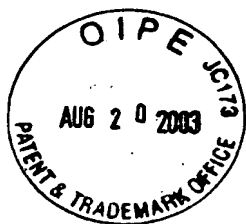


<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. TJU-2858	Application No. 10/621,684
		Applicant Scott A. Waldman	
		Filing Date July 17, 2003	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	21	Fitzgerald et al., "Adenovirus-Induced Release of Epidermal Growth Factor and pseudomonas Toxin into the Cytosol of KB Cells during Receptor-Mediated Endocytosis", <i>Cell</i> , <b>1983</b> , 32, 607-617	
	22	Fitzgerald et al., "Construction of Immunotoxins Using Pseudomonas Exotoxin A", <i>Methods in Enzymology</i> , <b>1987</b> , 151, 139-145	
	23	Giannella et al., "Development of a Radioimmunoassay for <i>Escherichia coli</i> Heat-Stable Enterotoxin: Comparison with the Suckling mouse Bioassay", <i>Infection and Immunity</i> , <b>1981</b> , 33, 186-192	
	24	Gros, O. et al. "Biochemical Aspects of Immunotoxin Preparation", <i>J. Immunol. Meth.</i> , <b>1985</b> , 81, 283-297	
	25	Guarino, A. et al., "T <sup>84</sup> Cell Receptor Binding and Guanyl Cyclase Activation by <i>Escherichia coli</i> Heat-Stable Toxin", <i>Am. J. Physiol.</i> , 253 (Gastrointest. Liver Physiol. 16): G775-780, <b>1987</b>	
	26	Gyles, C.L., "Discussion Heat-Labile and Heat-Stable Forms of the Enterotoxin from E. Coli Strains Enteropathogenic for Pigs", <i>Ann. N.Y. Acad. Sci.</i> , <b>1979</b> , 16, 314-321	
	27	Hakki et al., "Solubilization and Characterization of Functionally Coupled <i>Escherichia coli</i> Heat-Stable Toxin Receptors and Particulate Guanylate Cyclase Associated with the Cytoskeleton Compartment of Intestinal Membranes", <i>Int. J. Biochem.</i> , <b>1993</b> , 25, 557-566	
	28	Hugues et al., "Identification and Characterization of a New Family of High-Affinity Receptors for <i>Escherichia coli</i> Heat-Stable Enterotoxin in Rat Intestinal Membranes", <i>Biochemistry</i> , <b>1991</b> , 30, 10738-10745	
	29	Humm, J.L., "Dosimetric Aspects of Radiolabeled Antibodies for Tumor Therapy", <i>J. Nuclear Med.</i> , <b>1986</b> , 27, 1490-1497	
	30	Klipstein et al., "Development of a Vaccine of Cross-Linked Heat-Stable and Heat-Labile Enterotoxins that Protects Against <i>Escherichia coli</i> Producing Either Enterotoxin", <i>Infect. Immun.</i> , <b>1982</b> , 37, 550-557	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	Docket No. TJU-2858	Application No. 10/621,684
	Applicant Scott A. Waldman	
	Filing Date July 17, 2003	Group Not Yet Assigned
	Confirmation No. Not Yet Assigned	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>		
31	Krejcarek et al., "Covalent Attachment of Chelating Groups to Macromolecules", <i>Biochem. Biophys. Res. Commun.</i> , <b>1977</b> , 77, 581-585	
32	Kwok et al., "Calculation of Radiation Doses for Nonuniformly Distributed $\beta$ and $\gamma$ Radionuclides in Soft Tissue", <i>Med. Phys.</i> , <b>1985</b> , 12, 405-412	
33	Leonard et al., "Kinetics of Protein Synthesis Inactivation in Human T-Lymphocytes by Selective Monoclonal Antibody-Ricin Conjugates", <i>Cancer Res.</i> , <b>1985</b> , 45, 5263-5269	
34	Magerstaedt, M. et al. "Antibody Conjugates and Malignant Disease", CRC Press, Boca Raton, <b>1991</b> , 42-45 and 110-152	
35	Masuho et al., "Importance of the Antigen-Binding Valency and the Nature of the Cross-Linking Bond in Ricin A-Chain Conjugates with Antibody", <i>J. Biochem.</i> , <b>1982</b> , 91, 1583-1591	
36	Merrifield, "Solid Phase Peptide Synthesis. I. The Synthesis of a Tetrapeptide", <i>J. Am. Chem. Soc.</i> , <b>1963</b> , 85, 2149-2154	
37	Michel et al., "Fluorescence Studies of Nucleotides Binding to Diphtheria Toxin and Its Fragment A", <i>Biochim. et Biophys. Acta</i> , <b>1974</b> , 365, 15-27	
38	Moseley et al., "Isolation and Nucleotide Sequence Determination of a Gene Encoding a Heat-Stable Enterotoxin of <i>Escherichia coli</i> ", <i>Infect. Immunity</i> , <b>1983</b> , 39, 1167-1174	
39	Okamoto et al., "Substitutions of Cysteine Residues of <i>Escherichia coli</i> Heat-Stable Enterotoxin By Oligonucleotide-Directed Mutagenesis", <i>Infect. Immunity</i> , <b>1987</b> , 55, 2121-2125	
40	Richardson, T.C., "Astatine ( $^{211}\text{At}$ ) as a Therapeutic Radionuclide. The Plasma: Blood Cell Distribution in Vitro", <i>Nucl. Med. Biol.</i> , <b>1986</b> , 13, 583-584	
EXAMINER		DATE CONSIDERED





<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. TJU-2858	Application No. 10/621,684
		Applicant Scott A. Waldman	
		Filing Date July 17, 2003	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	41	Sack, "Human Diarrheal Disease Caused by Enterotoxigenic <i>Escherichia coli</i> ", <i>Ann. Rev. Microbiol.</i> , <b>1975</b> , 29, 333-353	
	42	Shimonishi et al., "Mode of Disulfide Bond Formation of a Heat-Stable Enterotoxin (ST <sub>h</sub> ) Produced by a Human Strain of Enterotoxigenic <i>Escherichia coli</i> ", <i>FEBS Letters</i> , <b>1987</b> , 215, 165-170	
	43	So et al., "Nucleotide Sequence of the Bacterial Transposon Tn1681 Encoding a Heat-Stable (ST) Toxin and Its Identification in Enterotoxigenic <i>Escherichia coli</i> Strains", <i>Proc. Natl. Acad. Sci. USA</i> , <b>1980</b> , 77, 4011-4015	
	44	Spitler et al., "Therapy of Patients with Malignant Melanoma Using a Monoclonal Antimelanoma Antibody-Ricin A Chain Immunotoxin", <i>Cancer Research</i> , <b>1987</b> , 47, 1717-1723	
	45	Steinstraßer et al., "Selection of Nuclides for Immunoscintigraphy/Immunotherapy", <i>J. Nucl. Med.</i> , <b>1988</b> , 29(5), 875	
	46	Strains, " <i>Proc. Natl. Acad. Sci. USA</i> , <b>1980</b> , 77, 4011-4015	
	47	Thompson et al., "Biological and Immunological Characteristics of <sup>125</sup> I-4Tyr and -18Tyr <i>Escherichia coli</i> Heat-Stable Enterotoxin Species Purified by High-Performance Liquid Chromatography", <i>Analytical Biochemistry</i> , <b>1985</b> , 148, 26-36	
	48	Thompson, M.R., " <i>Escherichia coli</i> Heat-Stable Enterotoxins and Their Receptors", <i>Pathol. Immunopathol. Res.</i> , <b>1987</b> , 6, 103-116	
	49	Thorpe, et al., "New Coupling Agents for the Synthesis of Immunotoxins Containing a Hindered Disulfide Bond with Improved Stability In Vivo", <i>Cancer Research</i> , <b>1987</b> , 47, 5924-5931	
	50	Vaandrager, A. et al., "Atriopeptins and <i>Escherichia coli</i> Enterotoxin ST <sup>a</sup> Have Different Sites of Action in Mammalian Intestine", <i>Gastroenterology</i> , <b>1992</b> , 102(4), 1161-1169	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. TJU-2858	Application No. 10/621,684
		Applicant Scott A. Waldman	
		Filing Date July 17, 2003	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	51	Waldman and O'Hanley, "Influence of a Glycine or Proline Substitution on the Functional Properties of a 14-Amino-Acid Analog of <i>Escherichia coli</i> Heat-Stable Enterotoxin", <i>Infection and Immunity</i> , <b>1989</b> , 57, 2420-2424	
	52	Wessels and Rogus, "Radionuclide Selection and Model Absorbed Dose Calculations for Radiolabeled Tumor Associated Antibodies", <i>Med. Phys.</i> <b>1984</b> , 11, 638-645	
	53	Worrell et al., "Effect of Linkage Variation on Pharmacokinetics of Ricin A Chain-Antibody Conjugates in Normal Rats", <i>Anti-Cancer Drug Design</i> , <b>1986</b> , 1, 179-188	
	54	Yoshimura et al., "Essential Structure for Full Enterotoxigenic Activity of Heat-Stable Enterotoxin Produced by Enterotoxigenic <i>Escherichia coli</i> ", <i>FEBS Lett.</i> , 1985, 181, 138-142	
	55	Franz et al., "The Production of <sup>99m</sup> Tc-Labeled Conjugated Antibodies Using A Cyclam-Based Bifunctional Chelating Agent", <i>Nucl. Med. Biol.</i> , <b>1987</b> , 14, 569-572	
	56	deSauvage et al., "Primary Structure and Functional Expression of the Human Receptor for <i>Escherichia coli</i> Heat-Stable Enterotoxin", <i>J. Biol. Chem.</i> , 266, <b>1991</b> , 17921-17918	
	57	Bailey's Textbook of Histology, 16 Edition, Coperhaven, et al., Williams and Wilkens, Baltimore, MD, pg. 404 ( <b>1975</b> )	
	58	Wide, "Solid Phase Antigen-Antibody Systems", Radioimmunoassay Methods, Kirkham, Ed., E & S pages 405-412, Livingstone, Edinburgh, ( <b>1971</b> )	
	59	Hardingham, J.E. et al., "Immunobead-PCR: A Technique for the Detection of Circulating Tumor Cells Using Immunomagnetic Beads and the Polymerase Chain Reaction", <i>Cancer Research</i> , <b>1993</b> , 53, 3455-3458	
	60	Aitken, R. et al., "Recombinant enterotoxins as vaccines against <i>Escherichia coli</i> -mediated diarrhoea", <i>Vaccine</i> , <b>1993</b> , 11(2), 227-233	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. TJU-2858	Application No. 10/621,684
		Applicant Scott A. Waldman	
		Filing Date July 17, 2003	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	61	Chelly, J. et al., "Illegitimate transcription: Transcription of any gene in any cell type", <i>Proc. Natl. Acad. Sci. USA</i> , <b>1989</b> , 86, 2617-2621	
	62	Chelly, J. et al., "Illegitimate Transcription: Application to the Analysis of Truncated Transcripts of the Dystrophin Gene in Nonmuscle Cultured Cells from Duchenne and Becker Patients", <i>J. Clin. Invest.</i> , <b>1991</b> , 88(4), 1161-1166	
	63	Cooper, D.N. et al., "Ectopic (Illegitimate) Transcription: New Possibilities for the Analysis and Diagnosis of Human Genetic Disease", <i>Ann. Med.</i> , <b>1994</b> , 26(1), 9-14	
	64	Field, M., "Role of Cyclic Nucleotides in Enterotoxic Diarrhea", <i>Mol. Cyclic Nucl. Res.</i> , <b>1980</b> , 12, 267-277	
	65	Giannella, R.A., "Pathogenesis of Acute Bacterial Diarrheal Disorders", <i>Ann. Rev. Med.</i> , <b>1981</b> , 32, 341-357	
	66	Kaplan, J.C. et al., "Illegitimate transcription: its use in the study of inherited disease", <i>Human Mutation</i> , <b>1992</b> , 1(5), 357-360 (Abstract only)	
	67	Negrier, C. et al., "Illegitimate transcription: its use for studying genetic abnormalities in lymphoblastoid cells from patients with Glanzmann thrombasthenia", <i>British J. Haematology</i> , <b>1998</b> , 100(1), 33-39	
	68	Rao, M.C. et al., "Enterotoxins and Anti-toxins: Enterotoxins and ion transport", <i>Biochem.</i> , <b>1984</b> , 12, 177-180	
	69	Barchel et al., "Radioimaging and Radiotherapy", New York ( <b>1983</b> )	
	70	Zippelius, A. et al., "Limitations of Reverse-Transcriptase Polymerase Chain Reaction Analyses for Detection of Micrometastatic Epithelial Cancer Cells in Bone Marrow", <i>J. Clin. Oncology</i> , <b>1997</b> , 15(7), 2701-2708	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. TJU-2858	Application No. 10/621,684
		Applicant Scott A. Waldman	
		Filing Date July 17, 2003	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	71	Chabalgoity, et al., "Expression and immunogenicity of an echinococcus granulosus fatty acid-binding protein in live attenuated salmonella vaccine strains," <i>Infection and Immunity</i> , June 1997, 65(60), 2402-2412	
	72	Karem, et al., "Differential induction of carrier antigen-specific immunity by salmonella typhimurium live-vaccine strains after single mucosal or intravenous immunization of balb/c mice," <i>Infection and Immunity</i> , December 1995, 63(12), 4557-4563	
	73	O'Callaghan, et al., "Immune responses in balb/c mice following immunization with aromatic compound or purine dependent salmonella typhimurium strains," <i>Immunology</i> , February 1990, 184-189	
	74	Mann, E.A., et al., "Comparison of receptors for Escherichia coli heat-stable enterotoxin: novel receptor present in IEC-6 cells," <i>Am. J. Physiol.</i> , 1993, 264, G172-G178	
	75	Aimoto, S., et al., "Chemical synthesis of a highly potent and heat-stable analog of an enterotoxin produced by a human strain of enterotoxigenic Escherichia coli," <i>Biochem &amp; Biophys. Res. Comm.</i> , 1983, 112(1), 320-326	
	76	Carpick, B.W., et al., "The escherichia coli heat-stable enterotoxin is a long-lived superagonist of guanylin," <i>Infection &amp; Immunity</i> , 1993, 61(11), 4710-4715	
	77	Garipey, J., "Importance of disulfide bridges in the structure and activity of Escherichia coli enterotoxin ST1b," <i>Proc. Natl. Acad. Sci. USA</i> , 1987, 84, 8907-8911	
	78	Hamara, F.K., et al., "Uroguanylin: structure and activity of a second endogenous peptide that stimulates intestinal guanylate cyclase," <i>Proc. Natl. Acad. Sci. USA</i> , 1993, 90, 10464-10468	
	79	Hidaka, Y., et al., "Disulfide linkages in a heat-stable enterotoxin (STp) produced by a porcine strain of enterotoxigenic Escherichia coli," <i>Bull. Chem. Soc. Jpn.</i> , 1988, 61, 11265-1271	
	80	Ikemura, H., et al., "Heat-stable enterotoxin (ST <sub>h</sub> ) of human enterotoxigenic Escherichia coli, (Strain SK-1), structure-activity relationship," <i>Chem. Soc. Of Japan</i> , 1984, 57(9), 2150-2156	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. TJU-2858	Application No. 10/621,684
		Applicant Scott A. Waldman	
		Filing Date July 17, 2003	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	81	Ikemura, H., et al., "Synthesis of a heat-stable enterotoxin (ST <sub>h</sub> ) produced by a human strain SK-1 of enterotoxigenic Escherichia coli," <i>Chem. Soc. Of Japan</i> , <b>1984</b> , 57, 2543-2550	
	82	Kubota, H., et al., "A long-acting heat-stable enterotoxin analog of enterotoxigenic Escherichia coli with a single D-amino acid," <i>Biochem. &amp; Biophys. Res.</i> , <b>1989</b> , 161(1), 229-235	
	83	Yoshimura, S., et al., "Chemical synthesis of a heat-stable enterotoxin produced by enterotoxigenic Escherichia coli strain 18D," <i>Chem. Soc. Of Japan</i> , <b>1984</b> , 125-133	
	84	Yoshimura, S., et al., "A heat-stable enterotoxin of vibrio cholerae non-01: chemical synthesis, and biological and physicochemical properties," <i>Biopolymers</i> , <b>1986</b> , 25, S69-S83	
	85	Carrithers, et al., " <i>Escherichia coli</i> heat-stable toxin receptors in human colonic tumors," <i>Gastroenterology</i> , <b>1994</b> , 107, 1653-1661	
	86	Carrithers, et al., "Guanylyl cyclase C is a selective marker for metastatic colorectal tumors in human extraintestinal tissues," <i>Proc. Natl. Acad. Sci. USA</i> , <b>1996</b> , 93, 14827-14832	
	87	Hugues, et al., Affinity purification of functional receptors for <i>Escherichia coli</i> heat-stable enterotoxin from rat intestine," <i>Biochem.</i> , <b>1992</b> , 31(1), 12-16	
	88	Urbanski, et al., "Internalization of <i>E. coli</i> ST mediated by guanylyl cyclase C in T84 human colon carcinoma cells," <i>Biochim. ET Biophys. Acta</i> , <b>1995</b> , 1245, 29-36	
	89	Orkin, et al., Co-Chair. Report and recommendations of the panel to assess the NIH investment in research on gene therapy, December <b>1995</b> , page 41	
	90	PCT International Search Report dated August 7, 1997, 1 page	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office				Docket No. TJU-2858		Application No. 10/621,684	
				Applicant Scott A. Waldman			
				Filing Date July 17, 2003		Group Not Yet Assigned	
				Confirmation No. Not Yet Assigned			
<b>U. S. PATENT DOCUMENTS</b>							
Examiner Initial		Document No.	Date	Name	Class	Subclass	
	91	5,160,723	11/3/92	Welt et al.	424	1.1	
	92	4,584,268	04/1986	Ceriani et al.	436	504	
	93	4,683,195	07/28/87	Mullis et al.	435	6	
	94	4,683,202	07/28/87	Mullis et al.	435	91	
	95	4,965,188	10/23/90	Mullis et al.	435	6	
	96	5,075,216	12/24/91	Innis et al.	435	6	
	97	5,237,051	8/17/93	Garbers et al.	530	350	
	98	5,518,888	5/21/96	Waldman	435	7.23	
	99	5,601,990	02/1997	Waldman	435	7.23	
	100	4,845,200	07/1989	Cullinan, et al.	530	391	
	101	5,057,313	10/1991	Shih, et al.	424	85.91	
	102	4,828,831	05/1989	Hannart, et al.	424	92	
	103	4,411,888	10/1983	Klipstein, et al.	424	92	
	104	4,499,080	02/1985	Duflot, et al.	514	12	
	105	6,268,159	07/2001	Waldman	435	7.23	
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>			



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office				Docket No. TJU-2858		Application No. 10/621,684	
				Applicant Scott A. Waldman			
				Filing Date July 17, 2003		Group Not Yet Assigned	
				Confirmation No. Not Yet Assigned			
<b>U. S. PATENT DOCUMENTS</b>							
Examiner Initial		Document No.	Date	Name	Class	Subclass	
	106	6,060,037	05/2000	Waldman	424	1.65	
	107	4,431,763	07/28/82	Zygraich			
	108	5,593,825	01/14/97	Carmen, et al.			
	109	5,443,816	08/22/95	Zamora, et al.	424	1.69	
	110	4,659,666	04/21/87	May, et al.	435	188	
	111	4,867,973	09/1989	Goers, et al.	424	85.91	
	112	4,963,263	10/1990	Kauvar	210	635	
	113	5,000,935	03/1991	Faulk	424	1.69	
	114	5,087,616	02/1992	Myers, et al.	514	21	
	115	5,133,886	07/1992	Kauvar	210	635	
	116	5,143,854	09/1992	Pirrung, et al.	436	518	
	117	5,217,869	06/1993	Kauvar	435	7.9	
	118	5,221,736	06/1993	Collidge, et al.	536	25.31	
	119	5,223,409	06/1993	Ladner, et al.	435	69.7	
	120	5,252,743	10/1993	Barrett, et al.	548	303.7	
	121	5,270,170	12/1993	Schatz, et al.	435	7.37	
	122	5,288,514	02/1994	Ellman	427	2	
	123	5,324,483	06/1994	Cody, et al.	422	131	
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>			



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	Docket No. TJU-2858	Application No. 10/621,684
	Applicant Scott A. Waldman	
	Filing Date July 17, 2003	Group Not Yet Assigned
	Confirmation No. Not Yet Assigned	

**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	124	5,338,665	08/1994	Schatz, et al.	435	6
	125	5,340,474	08/1994	Kauvar	210	198.2
	126	5,366,382	11/1994	Venton, et al.	435	7.1
	127	5,384,261	01/1995	Winkler, et al.	436	518
	128	5,395,750	03/1995	Dillon, et al.	435	5
	129	5,405,783	04/1995	Pirrung, et al.	436	518
	130	5,412,087	05/1995	McGall, et al.	536	24.3
	131	5,420,328	05/1995	Campbell	558	110
	132	5,424,186	06/1995	Fodor, et al.	435	110

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	133	83/9512	12/21/83	South Africa		

**EXAMINER**

**DATE CONSIDERED**